Reconsideration of the above-identified application is requested in view of the following remarks.

REMARKS

Status of the Claims

Claims 5-8 and 13-17 are currently pending, with claim 5 being the sole independent claim.

Claims 5-8 and 13-17 have been rejected.

Based on the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 103

The Examiner has rejected claims 5-8 and 13-17 under 35 U.S.C. § 103(a) as being unpatentable over the disclosures of Ibsen (USPN 5,147,655). Applicants respectfully traverse this rejection.

According to the Examiner, Ibsen is directed to "a method of administering an oral medicinal formulation comprising the administration of a foam composition into the oral cavity." See Office Action at page 2, section 4. The Examiner continues, "[t]he formulation comprising foaming agents and surfactants such as polyethylene glycol and sodium lauryl sulfate (col. 9, lin. 25-37). The formulation forms a foam around drug particles making the particle easier to swallow (col. 3, lin. 65-col. 4, line 11)." See Office Action at pages 2, section 4.

The Examiner further contends that "the claims differ from the reference by reciting various concentrations of active ingredient(s). However, the preparation of

various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention." See Office Action at page 3, section 5.

The Examiner concludes that "it would be within the level of skill in the art to follow the teachings and suggestions of the art in order to deliver an oral foaming formulation," and that "[i]t would have been obvious to follow these teachings with an expected result of a method of delivering drug particles to a patient with problems swallowing." See Office Action at pages 3, section 6. Applicants respectfully traverse this rejection.

The invention as presently claimed is directed to a "method for administering to a patient an aqueous oral medicinal composition comprising an active ingredient for internal use and at least one foaming agent, foaming said aqueous composition with air by ejecting said composition from a foam-developing device for administration depositing said foam in the oral cavity of a patient without added water, said patient swallowing said foam or allowing said foam to liquefy prior to swallowing." See Claim 5 (emphasis added). For patients with swallowing difficulties, such as aged persons, or people recovering from surgery, solid and/or liquid compositions can be particularly difficult to swallow and may lead to choking or other administration problems. See Specification at pages 2-3. The foam composition of the present invention can be easily administered causing no irritation during administration, without any water supply and does not cause choking. On the other hand, Ibsen is directed to "an oral composition which is adapted to be dispersed in an aqueous carrier substantially immediately prior to administration and which comprises a multiplicity of particles comprising an active

substance, said particles being combined with a gelling or swelling agent capable of forming a viscous medium around the particles in an aqueous carrier as well as being provided with a masking surface layer when dispersed in the aqueous carrier. See Ibsen at col. 2, lines 13-21 (emphasis added). It is precisely these types of solid and/or liquid compositions, which can be difficult to swallow, that the present invention seeks to avoid.

It is believed that the assertion of obviousness by the Examiner arises from the sole comment in Ibsen that "[i]t is contemplated that the masking surface layer on the particles may be provided by for instance a substance which will produce a foam around the particles on dispersion thereof in the aqueous carrier." See Ibsen at col. 3, lines 65-68. However, the Ibsen patent does not teach the use of foaming agents but rather only once mentions that the use of a foam is contemplated, as noted above. There is no teaching or suggestion in Ibsen how any such foam or foam composition would be formed. Importantly, Ibsen does not teach or suggest foaming a composition with air by ejecting the composition from a foam-developing device, as required by the present claims. See Claim 5. Furthermore, Ibsen does not teach or suggest any benefits associated with the use of a foam. Applicants assert that Ibsen is non-enabling as to the formation and/or use of a foam or foam composition in oral medicinal formulations.

In fact, Ibsen continues at column 3, line 68:

> However, in a currently preferred embodiment of the present invention, the masking surface layer on the particles containing the active substance is provided by an increased viscosity of the viscous medium in the immediate vicinity of the particles related to the viscosity of the surrounding aqueous carrier. In other words, according to this embodiment, the viscous medium forms a layer of a gelled mass with a higher viscosity than the rest of the viscous medium, this gelled mass surrounding the particles, and substantially each particle, of the composition.

See Ibsen at col. 3, line 68 through col. 4, line 11 (emphasis added). The only enabling disclosure in Ibsen is directed to drug particles that are surrounded by a gel and not a foam. Moreover, according to Ibsen "the gelling or swelling agent is a vital component of the present composition." See Ibsen at col. 4, lines 12-14 (emphasis added). Thus, Ibsen is specifically concerned with the use of one or more gelling or swelling agents for forming a viscous medium around an active substance in an aqueous carrier. No such gelling or swelling agent is part of the composition of the present invention. In contrast, as previously mentioned, the present invention is directed to "a method for administering an oral medicinal composition comprising an active ingredient and at least one foaming agent, which is ejected from a foam-developing device to prepare them into foam for administration." See Specification at page 4, third paragraph (emphasis added).

"To establish a prima facie case of obviousness of a claimed invention, all the claim limitations must be taught or suggested in the prior art." See M.P.E.P § 2143.03 (citing In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974)). The Ibsen patent does not teach or suggest the use of a foaming agent or the use of an air based foam composition but rather discloses a single non-enabling mention of foam and, in particular discloses the use of a gelling or swelling agent to create a viscous composition, which is the antitheses of the air based foam composition of the presently claimed invention.

The Examiner contends that Ibsen discloses polyethylene glycol and sodium lauryl sulfate as foaming agents at column 9, lines 25-37. Applicants respectfully disagree.

According to Ibsen, "locally increased viscosity of the gelling or swelling agent may be obtained by including a surfactant in the composition of the invention, thus

reducing the surface tension of the water in the aqueous carrier. Useful surfactants include ... polyethylene glycol and ...sodium lauryl sulphate." See Ibsen at col. 9, lines 25-35 (emphasis added). Thus, it is clear from Ibsen that polyethylene glycol and sodium lauryl sulfate are disclosed as surfactants for the purpose of increasing the viscosity of the gelling or swelling agent, and not as foaming agents, as the Examiner contents. Again, increasing the viscous, gelling or swelling are all objectives opposed to what Applicant wants to achieve.

Therefore, Applicants assert that Ibsen fails to disclose all of the limitations of the presently claimed invention, and does not contemplate the advantages of the claimed foam, and thus, cannot render the present invention obvious. Applicants respectfully request reconsideration and withdrawal of this rejection.

CONCLUSION

Applicants respectfully point out that Ibsen fails to teach or suggest all of the claim limitations of the present invention. Therefore, Ibsen does not and cannot render the claimed invention obvious to one of skill in the art. Applicants respectfully request reconsideration and withdrawal of the Examiner's rejection under 35 U.S.C. § 103(a).

Respectfully submitted,

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